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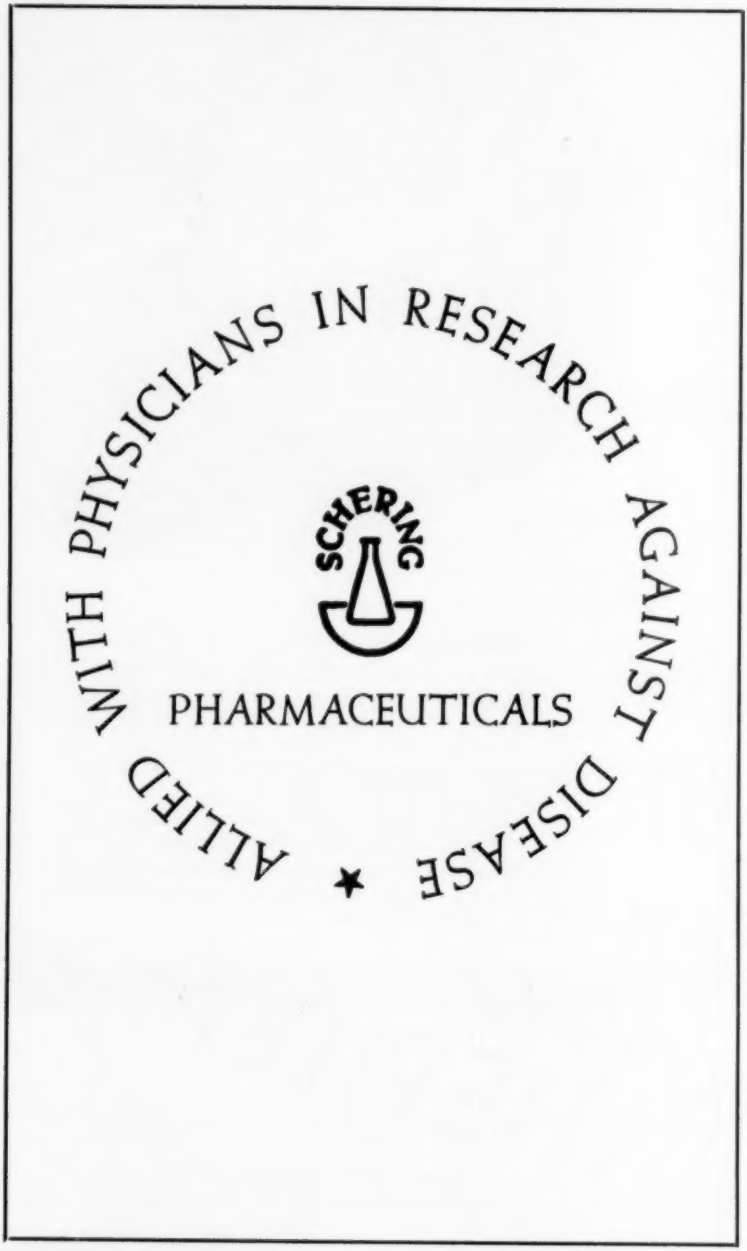
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EDITORIAL

CAN ARB SUCCEED?

IN this issue we present an article by Professor S. B. Jeffries on the very controversial "ARB" plan being advocated by certain segments of pharmacy as one approach to the correction of the problem of duplication of brands. We have published this because we believe that all sides of a controversy deserve to be heard.

In reading this article we were impressed by much of the sound logic conveyed by Professor Jeffries in developing his thesis, and we recommend this article as worthy of attention by both the antagonists as well as the protagonists of ARB. While the opponents of this plan undoubtedly will not re-align their thinking by reading this discussion, they will indeed find listed many of the arguments which must be refuted by equal logic if their opposition is to be effective. Statements based on purely subjective and emotional reactions will not suffice. That the widespread adoption of the ARB program would have a major impact on the present organization of pharmacy seems indisputable.

While certain aspects of the ARB plan look attractive and might be helpful, particularly to the retailer, we must admit of a certain reluctance to endorse the plan wholeheartedly. This we do without fear or favor, for the freedom of personal expression by the editor has been the continuing policy of this journal for many decades.

An analogy has been drawn by the advocates of ARB between it and the practice in hospitals of limiting drugs to those listed in the formulary. The analogy we fear is not quite correct. While it is true that in many hospitals only one brand of some well known drug is stocked *that* brand is selected not by the pharmacist alone but by and with the knowledge and consent of the pharmacy and therapeutics committee of the hospital. In this there is a very careful check on the reliability of the brand by staff physicians as well as the pharmacist. Usually it will be found that the supplier is beyond reproach.

The question which looms large in our thinking on this problem is whether ARB might not evolve into AB, "*any* brand." As a corollary to this we might then ask "Is the brand important?" To

answer this let us search our own conscience as pharmacists. While any brand may be quite good enough for John Doe what brand do we select for ourselves or our own sick children? Is it the "Cut Price Drug Co., Inc. of Smithville or is it one of our better, nationally known firms? Can we with absolute conviction and full truth state that all pharmacists have the same standards for themselves as for others? If they do then they are truly the elect of God, for in no other group of humans, professional or otherwise, is it so!

In the final analysis all of the stir about ARB may prove to be purely academic. A physician won't refer his wife to ARS (any reliable specialist) even though each is duly certified by his specialty board. This being so why is the physician so likely to overlook the inescapable flaw in the ARB proposal? He drinks one brand of coffee or whiskey, smokes one brand of cigarettes and wears an Arrow shirt. To make him totally unaware and unconcerned over the brand of drug his patient gets seems a monumental, if not impossible, task. Perhaps it can be done. Facetiously, we might suggest either a lobotomy, or chlorpromazine, t. i. d., administered by the enterprising pharmacist before he attempts to convince the physician of the unimportance of brand. This may induce him into that state wherein he is not brand conscious or conscious of anything else save his vegetative existence.

Our conviction is that brand duplication was a symptom of the rapidly expanding pharmaceutical industry over the past decade. As the readjustments of the leveling off process are made it will be uneconomic to duplicate all products made by others and this practice will become much less troublesome to the retailer. In the meantime we recommend somewhat cooler heads and tempers on the part of all, as this subject is considered and discussed.

L. F. Tice

PETROLATUM GAUZE

By Louis Gershenfeld *

PETROLATUM GAUZE is a fine mesh absorbent gauze impregnated with petrolatum (petroleum jelly, usually white petrolatum. It is employed as a bland, non-adherent, non-reactive, non-macerating emollient or dressing, packing or drain, serving a wide variety of medical and surgical uses. It is non-toxic and non-irritating, does not interfere with the natural body mechanism, and is non-absorptive, light and readily adjustable. A sterile product should be used.

Dressings

The author in preparing this presentation was interested in learning the extent of use of Petrolatum Gauze (P-J gauze) as compared to other dressings. In his files and elsewhere (gatherings over two decades) as well as in personal and written questionnaires, considerable data was obtained which, briefly summarized, indicates that P-J gauze is widely used; and all hospitals, large and small, now employ petrolatum gauze to some extent. They either prepare the same or purchase it on the open market. Much less frequently, and not too extensively as compared with the use of P-J gauze, other impregnated dressings are employed. However, all of the latter are medicated or so-called antiseptic dressings, the material for impregnation being an antibacterial agent or a drug, used either in the dry state or incorporated in a cream or grease base.

Use of Petrolatum Gauze

Apparently Petrolatum Gauze as we know this product today is one of wide use and is of comparative recent origin. Actually there is little in the literature indexed either under Petrolatum Gauze or Petroleum Jelly Gauze. In fact in many instances the listing of the product if found at all is erroneously named and listed under "Vaseline". It is important to recognize, for there is a tendency to forget, that the designation "Vaseline" is a brand name, and specifically, it

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is the Registered Trade Mark of the Chesebrough Manufacturing Company Cons'd. The term "Vaseline" is used for *all* products marketed by this manufacturer not only for white petroleum jelly (petrolatum) and yellow petroleum jelly (petrolatum), but for various medicated petroleum jelly preparations, camphor ice, lip ice, pomade, hair tonics, petrolatum gauze dressing, etc. Vaseline petroleum jelly is merely one of the "Vaseline" brand products. It therefore is not only wrong, but because of the trade-mark name it is illegal to employ the term "Vaseline" as a synonym or merely as a designation for Petrolatum or Petroleum Jelly alone, unless one refers to the "Vaseline" (brand of) Petroleum Jelly.

Lyle (1) in a paper on the "Disinfection of War Wounds By The Carrel Method" read before the Surgical Section of the New York Academy of Medicine on October 6, 1916 mentions that "gauze impregnated with yellow petrolatum is applied to the skin surfaces below the wound" and an illustration shows "gauze impregnated with yellow petrolatum to protect the skin". He does not indicate that a sterile product was used. However, DaCosta (2) quotes this description from Keen's book on the "Treatment of War Wounds" and mentions specifically that the product is sterile. Carrel and Dehelly (3) refer to "squares of gauze sterilized in vaselin" in their volume on "The Treatment of Infected Wounds". In contacts during the first World War period and thereafter, the author noted that gauze impregnated with boric acid ointment rather than with petrolatum was used (and also reported by others) as strips placed on the skin adjacent to the wound. Later objection was raised to the use of boric acid ointment, especially when application was made to large areas; and its use was discontinued to be replaced in most instances by petrolatum alone as the so-called "grease" or the latter containing various chemotherapeutic agents.

Among numerous personal communications are to be found the following comments. Dr. Lund of Boston (4) mentioned that his first experience with Petrolatum Gauze was in 1920, when the Carrel-Dakin treatment of wounds was being widely used. In the early forties, he used it in the treatment of burns. Referring to Petrolatum Gauze, he states, "There has always been some question as to the absolute sterility of such strips because of the difficulty of sterilizing certain bacteria in the presence of oil of any kind." Dr. Meleney of Columbia University College of Physicians and Surgeons (5) indi-

cates his "first experience with it was in 1916 and 1917, when it was used extensively to protect the skin around a wound treated with Dakin's solution. At that time a very fine meshed gauze was used and this was called Dakin's gauze—and still is, in our hospital". He refers to Petrolatum Gauze "in a number of published reports describing the use of zinc peroxide".

Petrolatum Gauze full length, folded or cut into strips or pads of various dimensions, has been and is being employed by itself or as an adjunct with other treatment for a wide variety of uses in medicine and surgery, such as a covering, dressing, packing, drain or plug for cuts, abrasions and other injuries, for incisions of the skin, subcutaneous tissue and in wounds, for surface treatment of all kinds of burns and skin affections, in fractures and cysts, in appendectomy drainage or as a drain in other areas, for immobilization in a plaster cast and in fractures (especially nasal bone fractures), in circumcision, and in major or minor surgery of the abdominal region, the genitourinary system, the thorax and respiratory system, the cranium, the extremities, in rectal and proctologic operations, in plastic and orthopedic surgery, and in industrial and military medicine. In a review of several hundred recently published medical and surgical volumes, valuable uses for Petrolatum Gauze were given. Actually the product in most instances was not listed in the index. However, if the individual surgical techniques are examined, it will be found that mention of the use of Petrolatum Gauze is included. It is not possible in this presentation to enumerate all or even many of the applications, uses and specific references, other than to mention some of the more important and representative quotations (which see below).

Official in U. S. P. XV

Petrolatum Gauze has proven of sufficient merit to be recognized in the forthcoming fifteen revision of the *United States Pharmacopeia*. The author, therefore, thought that this presentation would be of interest at this time. In the proposed monograph, the description indicates that it is absorbent gauze saturated with white petrolatum, employing the latter in an amount equivalent to not less than 400 per cent of the weight of the gauze. The two components are to be sterilized separately, the gauze in the autoclave and the petrolatum by dry heat; the finished product then prepared by aseptic

manipulation is to be sterile. It must meet the requirement of the U. S. P. Sterility Tests for Oleaginous Materials. Each batch is to be tested for sterility by this or other adequate procedures after the preparation and sterilization of the Petrolatum Gauze. A labeling requirement concerning the packaging to be included in the monograph conforms with the opinion generally held by the Food and Drug Administration; that if the package reveals any evidence of damage or has been opened previously the sterility cannot be guaranteed. In practice, it means that bulk packaging of Petrolatum Gauze for marketable purposes is not approved. There is a similar requirement in the case of sterile sutures.

Preparation and Sterilization

In view of what has been said previously, it is surprising that the usual old and current pharmaceutical, medical, bacteriological and pharmacological textbooks and volumes specifically referred to as formularies do not even list this product, let alone indicate how it is prepared and sterilized. It is to be understood that Petrolatum Gauze when used on humans and animals is to be a sterile product. As is the common practice, it is important to mention again that all sterile surgical dressings usually bear (and should include) a statement that the sterility of the contents cannot be guaranteed if the package bears evidence of damage or has been previously opened. Surgical dressings, therefore, must be properly cared for in order to preserve the sterility of the contents, and must be kept in their original sealed condition. Packages are not to be opened and the contents exposed, except at the time of use.

The observations above were made after examining several hundred textbooks. In fact, among some sixty odd hospital formularies, where one would expect to find that this product is included, there was only one which mentioned such a preparation, merely indicating that it was available. Not one of them included its method of preparation and sterilization. The formulas of medicated gauzes, however, are noted in many textbooks. The *British Pharmaceutical Codex* (6) and the *Pharmaceutical Recipe Book* (1st edition) (7) list several, the latter including eleven medicated gauzes, but no mention is made of Petrolatum Gauze. In the Codex (6), p. 1031, there is included a Paraffin Gauze Dressing, but this actually is a medicated dressing, as it contains balsam of Peru. It may be noted that on p. 1437, men-

tion is made of dry heat sterilization of dressings impregnated with soft paraffin, but as will be noted later, the sterilization techniques are inadequate.

The only important widely recognized medical and surgical book which mentions the preparation and sterilization of this product is that of Walter (8). He indicates that "It takes seventy minutes for 30 cc. of petroleum jelly on 30, 5 cm. x 15 cm., layers of 40 x 42 gauze in a shallow metal container to reach 160° C. One hundred sixty additional minutes are necessary to destroy spores on the gauze". One gathers from this statement that he recommends dry heat at a temperature of 160° C. for 2½ hours.

Two other sources usually known only by workers concerning themselves with sterilization techniques and sterilizing equipment are Beckett and Berman's volume on *"Sterilization and Disinfection"* for nurses (9) and several editions of *"The Manual"* (10) and their volume on *"A Text Book on Sterilization"* (11) published by the American Sterilizer Company.

In the Beckett and Berman volume, there is no mention of Petrolatum Gauze, but under anhydrous materials, they do consider petroleum jelly, recommending autoclaving "at 250° F. for about one hour to one hour and a half". They further state: "we have however, found very few, if any institutions, which follow the practice of dry heat sterilization on these materials. Some of them in fact, abandoned the practice shortly after having had disagreeable experiences in the way of spontaneous ignition of petroleum jelly in the dry heat oven." On the other hand in instructions issued for sterilization in Scanlon-Morris High Pressure autoclaves (12), the following is noted: "We do not recommend that the sterilization of Vaseline or talcum be attempted in an autoclave. . . . Vaseline and talcum should be sterilized in an oven (dry heat sterilization at 320° F. for one hour.") The American Sterilizer technique gives a detailed procedure of preparation and recommends "sterilization in the hot air oven at 320° F. (160° C.) for 2½ hours."

Among the many books on nursing and especially surgical nursing, there were no recent references. However, the following comments were noted concerning the preparation and sterilization of Petrolatum Gauze. The "Preparation of Vaselin Gauze" is detailed as follows by Eliason, Ferguson and Forrand (13): "It is best prepared in strips of bandage gauze six to eight inches long. They are

sprinkled with water to produce steam for sterilization and placed in a long narrow container (the so-called bacon can of the Army serving this purpose very admirably). The strips are covered with a layer of vaselin about a half inch thick and are sterilized for 30 minutes in the autoclave. . . . It is usually best to make no more than 20 strips at a time and if two containers are used the one can be resterilized after each use, the other being held in reserve. Vaselin gauze is effectively sterilized in the hot-air oven." Stafford and Diller (14) recommend the following procedure: "by placing strips of gauze in a covered, hinged tin box, such as the quart sized ice cream box. No more than 4 ounces of petrolatum is used and the number of layers of gauze is limited to a thickness of one inch. More gauze would not become properly impregnated with this amount of petrolatum, and the use of more petrolatum would necessitate a longer sterilizing time. It is sterilized by exposure for two hours in hot air at 300° F."

Frequent references concerning the preparation and sterilization of Petrolatum Gauze are also given in the "Question Box" of *Hospital Topics* (15) and in response to letters from readers in the *American Journal of Nursing* (16). The *Hospital Topics* recommends sterilization of Petrolatum Gauze "in dry heat at 320° F. for one hour; or dry heat at 250° F. for four hours. For larger quantities or larger sheets of vaseline gauze, expose to saturated steam at 250° F. for 30 minutes; turn off steam to chamber and expose to dry heat at 250° F. for four additional hours." In another reply, the statement is made that "In dry heat at 250° F., it takes six hours to kill dry resistant spores." The reply in the *American Journal of Nursing* is answered by Beckett as above (9), he being the technical director of the Aseptic Thermo Indicator Company.

In a new 1954 publication (17), Perkins in a chapter on "Bacteriological and Surgical Sterilization By Heat" details on pages 712 and 713 a procedure for the preparation of Petrolatum Gauze (though the product is not listed in the index). If it forms a layer ½ inch deep in the tray, it is to be sterilized "in the hot air oven at 160° C. for 2½ hours." He, as director of research of the American Sterilizer Company, repeats the technique recommended by the latter and mentioned above. However, the following additional comment concerning Petrolatum Gauze is of interest: "With this material a somewhat longer period of exposure is required than in the case of oils, due

principally to the increased depth of the layer in the tray. If the temperature is maintained within the range of 160° to 166° C. (320° to 330° F.) there should be no evidence of charring or discoloration of the gauze. Repeated tests have shown that a temperature of 170° C. (340° F.) will produce some discoloration, while a temperature of 182° C. (360° F.) for a short period of time produces definite charring of the gauze." However there is no mention made as to whether the two components were altered in any way at the 160° C. temperature, so that they do or do not conform to U. S. P. requirements.

Sterile Bulk P-J Dressings

In practice the absorbent gauze used in preparing Petrolatum Gauze is not necessarily sterile or sterilized. If it happened to be stored for long periods of time or used in the open field, it is not uncommon to find it is even more contaminated than originally, either due to damaged wrappings or exposures. However, "fortunately" in most instances the gauze used is comparatively clean, but of course not sterile. The petrolatum used, though low in or probably free of bacteria in most instances, frequently becomes contaminated on the surface due to the fact that the usual large bulk package employed for all purposes in the hospital is also employed for the preparation of the Petrolatum Gauze. Surface contamination may occur due to exposure when the petrolatum container is frequently left uncovered, or from unclean spatulas or scoops used to obtain the desired quantity needed. Certainly the least that can be done is to use clean gauze and to preferably use small bulk containers of petrolatum and keep these for the specific use of preparing the Petrolatum Gauze.

In the hospital, Petrolatum Gauze is usually prepared in bulk by nurses either by or under the supervision of the nurse in the operating room or in the Central Supply Room. It appears that in the case of the latter, hospital pharmacists or pharmacy interns especially in the large hospitals are now being used in some instances as supervisors. Accordingly, hospital pharmacists may necessarily in the future, but always should be interested in all details as it concerns this preparation.

There appears to be no satisfactory uniform technique used in practice. Unfortunately at times, one will find that in hospitals, those entrusted with the preparation of Petrolatum Gauze feel it is a menial chore. The home-made techniques vary widely as to details of prep-

aration. Different kinds of containers are used. The size of the gauze and the number of strips and thickness of the latter used and the packing into containers (loosely or tightly) vary. The amount of petrolatum added is not always proportioned to the amount of gauze employed. In few instances, very small quantities of water are added to the whole mass or to the gauze alone, though in most cases this is not included. All use a sterilization procedure in the final container, either the autoclaving technique (in the majority of instances) or the dry heat method. Only occasionally is each component sterilized separately, then mixed aseptically or mixed and the final product sterilized. The mode of storage of the containers with the bulk Petrolatum Gauze is frequently objectionable. They are either draped with muslin or most frequently left undraped (sometimes dated, usually not); and they are not always kept on closed shelves. Once the container is opened, resterilization is practiced by some; in other instances, however, the residual dressings are used without resterilization.

The author has noticed in the preparation of Petrolatum Gauze in various hospitals that there is considerable wastage because of carelessness and improper technique; all of which, of course, is infrequently considered for this individual item, nevertheless does add to an increase in its final cost. Also add to this, the cost of waste, equipment clean-up and time consumed by personnel. In many, if not most instances, the finished product cannot be regarded as being pharmaceutically elegant. Upon inspection, foreign particles and threads, frays or strings of gauze fibers are frequently found in amounts above that to be regarded as a maximum allowance. At times the entire gauze mass may not be completely impregnated or saturated with petrolatum. More frequently there is not an even or uniform distribution of dispersion of the petrolatum, so that the mass of gauze covered unevenly and at times too heavily with the petrolatum gives an appearance which is messy. Excessive amounts of petrolatum are apt to cause maceration of tissue.

In hospitals and institutions Petrolatum Gauze is always prepared in bulk. Note the authors previous comment concerning a guarantee of sterility after the removal of one or more strips. It is also to be noted that some hospitals do not have their sterilizers inspected periodically to insure proper performance or whether the recorders are registering correctly. In the preparation of bulk Petrolatum

Gauze, it is infrequent that the one who is sterilizing this product takes cognizance of the fact that the recorded temperature of the sterilizing apparatus in the technique used may not necessarily be the temperature of the Petrolatum Gauze under treatment. The latter is a non-conductor of heat; and during sterilization, some time is usually required before the bulk contents in a container reaches the same temperature as noted on the thermometer of the sterilizer or as automaticaly recorded. In the meantime, the exposure at a given temperature may be timed by the operator as soon as the desired temperature is noted or recorded, rather than beginning the timing after the proper temperature has been reached in the container, where the *bulk* Petrolatum Gauze is found. For instance, the recorded temperature of 160° C in a hot-air oven may not necessarily mean that this is the same temperature as present in the bulk Petrolatum Gauze package. As noted, it takes time before the latter will be at the same temperature, the length of time varying and depending upon such factors as the number of layers, size of each layer and the method of preparing each individual unit.

I have also found during my survey that in hospitals and institutions no attempt is made to test the finished product for sterility. Positive controls with known spore bearers (aerobes and especially anaerobes), as additional evidence that the sterilization technique is satisfactory, are rarely included and tested. If sterility testing of Petrolatum Gauze occurs at all in a hospital, it is infrequent if not rare. It is also true that the present U. S. P. and N. F. technique (they are both the same) has failed to obtain 100 percent positive findings in all known contaminated Petrolatum Gauze samples (as well as in that of other oleaginous substances), so that negative findings do not necessarily exclude the possibility of microorganisms being present.

Single Sterile P-J Dressings

Assuming that the home-made preparation meets all requirements, it is apparent that bulk preparations cannot be easily stored and especially made readily available for use in office practice, or carried in the physician's grip and in first aid kits, or handled in general transportation or in the field (as during warfare) with an assurance of the safety of sterility of each individual unit, especially after the bulk package is opened. Single sterile dressings in properly sealed sterile containers or packages to assure sterility until used is the ideal

practice to follow. Furthermore, the methods of preparation and sterilization in the final package or container used at present in many if not most hospitals are open to suspicion and may leave one trained in these problems with the feeling of uncertainty as to the sterility of Petrolatum Gauze in these institutions. It may be difficult to trace an infection as being specifically caused by a contaminated sample of Petrolatum Gauze for reasons which are obvious. It also is possible (and this is more frequently the case) that the contaminants are few, relatively non-resistant, and that they are probably not pathogens. Certainly if one is to market Petrolatum Gauze, only individual properly sealed packages in which the contents are kept sterile until used should be made available. Furthermore the method used for sterilization is of concern for the following reasons:

(1) The Petrolatum Gauze must be sterile.

(2) The gauze and the petrolatum must not be altered in any way by the sterilization technique, as at the time of use both must meet the U. S. P. requirements given under the respective monographs.

Autoclaving of samples of Petrolatum Gauze in the final container (at 121° C.) will not yield at all times a sterile product and perhaps never if the contaminants are spore bearers or are present in large amounts. One cannot help but feel dubious of the efficiency of the autoclaving procedures for Petrolatum Gauze as used in the final container.

The use of dry heat employing an adequate temperature for sterilization in the final container usually has a deleterious effect on Petrolatum Gauze and the finished product is apt to be of poor quality. The dry heat may discolor the petrolatum or affect the gauze (either the tensile strength or other characteristics) or impart an odor, so that the individual components will not meet U. S. P. requirements. In some instances, it may be only the pharmaceutical elegance that is affected, but this is objectionable.

Irradiation of Petrolatum Gauze in the final container with high voltage electrons at levels of dosage which would be tolerated by the product (without altering it in any manner) has as yet not been found satisfactory to yield a sterile product at all times.

The suggested method of preparation given in the forthcoming (fifteenth) revision of the U. S. P., using sterile components and an

aseptic technique for final formulation is the answer. Individual packaging is also of importance. It is of interest to note that for more than a decade, there has been marketed ready-made Petrolatum Gauze strips of various sizes in individual foil envelopes or packages, sterile at all times.* They are accordion-pleated with white petrolatum lightly impregnated in an amount to avoid maceration and evenly and uniformly distributed or dispersed, available for easy handling quickly, anywhere, anytime, in quantities as may be required. There is no wastage or spoilage, no delay or inconvenience and it possesses an unlimited storage life.

In the near future, the author and his associates will present a paper on the preparation and sterilization of Petrolatum Gauze and another, giving a more rigid technique for the sterility testing of this product.

Indications

The many uses for Petrolatum Gauze were mentioned briefly above. More detailed considerations are included here giving especially brief comments. If the literature for the past two decades is closely examined, a voluminous amount of references are noted especially if the body of each presentation is examined, as the summary or index may not always include a reference to Petrolatum Gauze. Though many of the titles are noted in the references, only a few quotations are mentioned here and are limited in the main to the literature of the last five years, which supplies the most frequently recommended present-day practices.

Burns

There are numerous problems to be considered in the treatment of burns, however they may have been brought about. It is not possible to consider even the scope of the burn problem, let alone explore the history of the management of burns. It will be sufficient to list the recent references that concern the local treatment, and to quote just a few of the more important references concerning the use of Petrolatum Gauze as one of the aids.

Since the exposure (open-air) method of treating burns was reintroduced in 1948, the question has arisen whether this procedure or the closed dressing technique (with or without pressure) is the

* Manufactured by the Chesebrough Manufacturing Company Cons'd.

one to use. Perhaps it is best at the start to give some quotations from a very recent article on the subject by workers from the Army Surgical Research Unit who appear to favor, wherever possible, the exposure method. Captain Reiss and Major Artz (18) state: "Despite our satisfaction with exposure as it is practiced at our Unit and with the acceptance that this method has been given throughout the country, there are certain burns that can only be managed adequately by the application of dressings. In the hands of experienced physicians, the dressing technique has outstanding merit. It is unique among the many forms of local care that have been advocated in that it is applicable in all burns, regardless of extent, location, depth, or complication injuries; there are no contra-indications to the use of dressings in normal peacetime practice." In dressing thermal injury after atomic bombing, they state: "In preparation for possible disaster, the development and stock-piling of plasma expanders and of large universal protective dressings is unquestionably a step in the right direction." In a symposium on burns sponsored by the National Research Council (19), Lieut. Colonel Pulaski in speaking of the exposure method states among other negative points as to its practical value: "First and foremost (and I wish to make this emphatic), it is a hospital procedure. This is not a treatment for the private physician to initiate and send the patient home." Also, "no meddling with the crust should be tolerated"; obviously close supervision and an unusual amount of proper education are necessary. During this same symposium, Prof. Brown (20) of Washington University in St. Louis constantly refers to the use of a fine mesh grease gauze for the protection of the wound and that this "treatment well carried out is one of the best and kindest methods yet devised." Of interest also is the comment by Dr. Harvey S. Allen (21) of Northwestern University Medical School who, in speaking of his use of Petrolatum Gauze, states: "The vaseline gauze is not heavily impregnated. It is a very thin single layer and you can actually see through it. We believe that much of the maceration which occurs following this method has been due to the large amount of vaseline which has been put on the wounds, which we all know will very quickly macerate." Commander Tolins (22), in speaking of the method of local care used for burns by the Navy, mentions frequently the application of a layer of sterile fine mesh "vaseline gauze" or a "vaseline-gauze pressure dressing". In *New York Medicine* presentations on the

treatment of burns in the event of atomic bombing, warnings are given against the use of home remedies, triple dyes, tannic acid, medicated ointments, etc., and Petrolatum Gauze is advocated (23). Cristopher (24) in considering the primary surface treatment for burns states: "Petrolatum and gauze is currently the treatment of choice." Sulzberger & Wolf (25) state that "after gentle cleansing and necessary 'wound toilet' protective and compression dressings—sterile petrolatum and gauze pads with superimposed plumbers' waste compressed with gauze windings—are generally considered excellent therapy". In the Therapy of Burns, Rehfuss and Price (26) recommend "Pressure bandage with sterile petroleum gauze".

Rush (27) makes the following interesting comment: "Burned hands should be soaked in warm saline baths and full range of motion established as soon as possible; between baths the hands should be covered with vaseline gauze to prevent hard crusts from forming which will limit motion. Fabricant (28) discussing burns of the auricle states: "Today, simple pressure dressings of petrolatum gauze combined with chemotherapy or antibiotics when indicated are sufficient for most burns," and Burnett (29) advises that "Vaseline gauze is the time-honored ointment dressing . . . vaseline has been more universally accepted and causes few skin reactions". Lam (30) mentions a study which "was made of the methods of treatment of minor burns in the plants of three large automobile companies. It was found that no less than eighty-four different substances were used in the treatment of 5609 burns". On the basis of the study referred to above, recommendations for the treatment of minor industrial burns were made. They were:

> "(a) Wash the area with soap and water, if it is dirty."
>
> "(b) Do not break blisters or otherwise 'debride' the wound."
>
> "(c) Cover with fine mesh gauze impregnated with petrolatum jelly."
>
> "(d) Apply a firm dressing over this, bulky enough to keep dirt away from the injury but not too large to keep the man off his job."

There are many other references in which Petrolatum Gauze is recommended for local treatment in the management of burns; only the recent references are given (31-46).

Surgery-Injuries-Fractures—The frequent use of Petrolatum Gauze in all kinds of surgery is found in all recent textbooks on surgery. Many of these references compare with comments by Lowry and Curtis (47) who report on 1700 traumatic wounds during World War II and MacFee's comments (48) who, in discussing the surgery of World War III, indicates that as part of the standard treatment of wounds at the field and evacuation hospital levels, "a light packing with vaselinized gauze" was used and the latter also was employed to aid the closure of wounds. The same author (49), in discussing the treatment of open wounds of the chest, recommends the following: "Temporary closure can be effected by means of a pad of petrolatum gauze." In the treatment of soft tissue injury complicating compound fractures, Giesen (50) advises that the "wound should be packed open with Vaseline gauze strips so that all cavities will drain properly". In the management of all kinds of nasal injuries, P-J gauze dressing is advocated as a packing and local protective covering by Bryant (51) and Seltzer (52). Myerson (53) recommends a packing of Petrolatum Gauze in the nose "for bleeding which complicates surgery or accidental injury". In the control of nasal hemorrhage, he states that "firm packing with Petrolatum Gauze will usually control it". Key (54) and Thompson (55) advocate the use of Petrolatum Gauze in the treatment of compound fractures.

Macomber (56) in a presentation of flat surface grafting indicates: "we believe that antiseptic precautions, frequent nonadherent dressings of ointment impregnated fine mesh gauze or silk or nylon cloth of one's choice, respect for patients' feelings, and early closure of wounds with split skin grafts are more important than any combination of so-called *recent* innovations. Open air treatment is not new, but has had a recent inning. In case of catastrophic burning of hundreds or thousands of people, it might become necessary for reasons of economy. However, most of us believe that dressings—as above—plus many hours of kind attention by interested doctors and nurses constitute the primary considerations in the management of burns."

Bailey (57) states that: "Vaseline Gauze as a material for drainage is free from the objections of plain gauze as far as the absorption of pus and blood is concerned, and some surgeons employ it in preference to rubber drainage tubes." Haynes and McGuire (58) indicate that: "Petrolatum gauze over the incision bone" is placed

thereon after the removal of sutures in neurosurgical procedures. It is employed in the treatment of hand injuries (59-61), eye injuries (62) and for circumcision (63, 64). Finestone (65) in discussing the technique of excision and primary closure of pilonidal cysts employs, "A piece of Vaseline gauze over the wound," a procedure employed by Korb (66). It also is used in actual cautery surgery in dermatology (67), in indolent ulcers of the skin (68), in gynecology (69), in proctology (70), as a colostomy dressing (71), etc. Civilian defense (72, 73, 74), first aid kit requirements (75, 76, 77) and recommendations to the physician at a seminar as to "what belongs in the physician's bag" (78) include the advice of having always available sterile Petrolatum Gauze.

Summary and Conclusions

Petrolatum Gauze has proven of sufficient merit to be recognized in the forthcoming fifteenth revision of the United States Pharmacopeia. This presentation should therefore be of interest at this time. The author found little in textbooks, formularies and in the literature, especially as it concerns the preparation and sterilization of this product. Though widely used today in almost all hospitals, he found that there was no uniform satisfactory technique employed in practice at these institutions, where Petrolatum Gauze is always prepared in bulk. The home-made techniques vary widely as to details of preparations; and one cannot help but feel dubious of the efficiency of the procedures of preparation and sterilization, as to their yielding at all times a sterile product and one possessing pharmaceutical elegance. Many of the problems involved are detailed. Numerous references concerning a wide variety of uses are given. It is apparent that bulk preparations cannot be easily stored and especially made available for use in office practice or carried in the physician's grip and in first aid kits, or handled in general transportation or in the field (as during warfare) with an assurance of the safety of sterility of each individual unit, especially after the bulk package is opened. Single sterile Petrolatum Gauze dressings in properly sealed sterile containers or packages, to assure sterility until used is the ideal practice to follow. To assure a pharmaceutically elegant, sterile product and one in which the individual components have not been altered in any way by the sterilization technique, the suggested method of preparation given in the forthcoming (fifteenth)

revision of the United States Pharmacopeia, using sterile components and an aseptic technique for final formulation is the answer. It also is important to recognize that the finished product should be tested for sterility to be assured that it is sterile. Furthermore, spot checks, using positive controls with known sporebearers (aerobes and especially anaerobes) are to be included in the processing, as additional evidence that the sterilization technique used is satisfactory.

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THE EFFECT OF SUBSTITUTION, DUPLICATION AND THE GENERIC-NAME, "ARB" PRESCRIPTION WRITING CONCEPTS ON THE ECONOMICS OF PHARMACY *

By S. B. Jeffries **

THE economic, sociological and legal forces currently at work in the Pharmaceutical field are sure to make 1954 a milestone year in the annals of modern pharmacy. Traditional patterns of medicinal and proprietary production, brand-name distribution and marketing are in imminent danger of being upset. Long overdue changes in retail professional practices and professional education are taking place all around us, and sociological concepts dealing with public health and medical care are being critically revaluated in terms of the needs of a better informed, growing and aging population.

The full impact of these forces on retail professional pharmacy is reflected in the emergence of such acute ethico-economic problems as substitution, duplication, and the adoption of the "generic-name, ARB" concepts of prescription writing and dispensing. Professional competition from industrial, union and group medical plans offering prescription services to their members and subscribers is on the increase and threatens to cut deeply into drug store professional potential. The rate of growth of prescription inventory investment appears to be outstripping gross returns as well as net returns without relief in sight. The returned goods problem, too, is affecting all segments of the drug field with many top manufacturers tending to tighten rather than relax their returned goods policies. Guaranteed sale of prescription legend drugs is, for all practical purposes, more theory than actuality.

One of the most fundamental of the bread and butter economic problems facing modern pharmacy is the growing sensitivity of the public to the high cost of medical care. Without trying to make a case for the exponents of the view that medical care costs are high,

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we should take cognizance of the fact that the U. S. Department of Commerce reported a figure of $9 billion for medical care expenditures for 1952. However, many public health authorities claim that the total for medical care exceeded $10.5 billion, and the cost of illness was greater than $15 billion. Expenditures for drugs and drug sundries were slightly in excess of $1.6 billion, or roughly a per capita consumption of drugs and sundries of slightly less than $10.00. Compare this with the 1952 per capita expenditure of $55.00 for alcoholic beverages and $32.00 for tobacco products.

The truth of the matter is that the public is purchasing health and life at a phenomenally low figure . . . at true bargain rates . . . but the public does not know about it. The situation is quite to the contrary. Mr. and Mrs. Consumer feels that medical care costs are way out of line . . . and that "something ought to be done about it by somebody". Rightfully or wrongfully, the consumer vents his dissatisfaction with the situation on his neighborhood pharmacist.

The customer knows little or nothing about the actual cost of the medicinal ingredients, the professional skills, or the labor and overhead involved in making a prescription available. All he knows is that his illness was both annoying and expensive, and the $6.50 he had to spend for a prescription of 30 capsules was outrageously painful. A recent survey on consumer reaction to medicine costs revealed that more than 63% of the respondents felt that prescription prices were higher than they should be, and more than half blamed high prices on "high profit taking by retail pharmacy".

This public agitation about high medical care and drug costs is not helped by the continuous name calling and blame passing carried on by the various elements in the pharmaceutical and medical supply line. Not too long ago a top pharmaceutical company executive told a New York City newspaper reporter that it is the neighborhood druggist who is largely responsible for high medication costs. Physicians, frequently as poorly informed as the average consumer about the "cost" story behind prescription dispensing, add to the confusion by openly criticising the pharmacist on the matter of price, relying for the most part on half disclosed price facts and prejudices picked up from misdirected manufacturers' representatives. Needless to say, many thoughtless pharmacists add to the noise, shouting "I accuse" and pointing their fingers at one or another segment of the pharmaceutical field, little realizing that the umbrella of public suspicion and dissatisfaction covers them as well.

With medical care costs soaring into the billions it is easy to understand how an irritated, cost-suspicious public might easily fall for socialistic propaganda and be persuaded to believe that the corner pharmacy was taking high profits on the misfortunes of others and "rolling in wealth". Actually, quite the opposite is true.

For example—quoting from the 1952 Lilly Survey—62% of the drug stores in cities of 500,000 plus population, operated at a loss, or had a net profit of less than 4% of sales. 23% of all drug stores reporting operated at a loss, or had a net profit of less than 2% of sales. And almost 50% of the drug stores in the $75,000 to $100,000 volume category earned from less than 1% to 4% net profit.

The facts show pretty clearly that pharmacists are not rolling in wealth, and they are finding it more and more difficult to deal with consumer medical care price prejudices on the one hand and increasingly burdensome operational and professional capital costs on the other. In a professional operations study recently conducted in this area in conjunction with the development and distribution of the Jeffries "Universal Prescription Costing and Pricing Calculator", it was found that:

1. A substantial number of drug stores were realizing little or no net profit on prescription department operations.

2. Prescription department unit and dollar inventory levels were higher than ever before.

3. The rate of increase of prescription inventory was at an all time high with returns on capital invested in professional department inventory at a new low despite increased dollar volume. A return of 4 to 6% on capital investment in prescription inventory was not unusual. It might be noted that many common stocks, bonds and mortgages are showing a much higher yield. It is not unreasonable to expect a yield of between 20 and 25% on capital invested in this type of inventory in the light of the many risks involved.

4. Operational and occupancy costs were higher with little prospect of a downward adjustment.

Obviously the pharmacist is on the hook. Hemmed in by external pressures in the form of consumer "price" prejudices and beliefs, he

is in no position to effect sweeping external prescription price adjustments. By the same token he is powerless to keep the lid on operating expenses. In a word he is in a "bread-and-butter" squeeze. The pharmacist's dilemma is pinpointed by the current Schenley price situation. How can the operating pharmacist explain to an irate customer or physician the overnight increase in the cost of Dobrane from $1.80 to $4.50 per hundred, or Sedamyl from $4.00 to $9.00 per hundred, or Titralac from $1.50 to 3.00 per hundred. Whether this increase is or is not justifiable is not the issue. How much of this increase will the pharmacist have to absorb to placate his customers and physicians? (The above has been taken care of recently by correction.)

While the solution to this economic problem is not likely to be achieved easily, we might approach it by suggesting that pharmacists lay to rest once and for all the many out-dated and so-called traditional marketing and gross margin concepts that the pharmaceutical field has been burdened with for these many years, and replace them with sound, realistic marketing, pricing and discount policies geared to meet current retail operational needs. There is nothing sacrosanct about traditional gross margin percentages or the brand-name ethical marketing structure. Improvement in both these areas may very well be indicated.

And who will deny that this is the right time to develop a dynamic pharmacy-medical professional relations program calculated to bring about a deeper understanding of the professional and economic needs of both? In line with this thinking, retail pharmacy might take a new and longer look at the magnificent professional relations and educational job our top hospital pharmacists are doing with staff and visiting physicians.

In one leading New York City hospital (Lenox Hill), the Pharmacy Department holds regularly scheduled classes for student and registered nurses, internes, staff and visiting physicians on formulary use, prescription writing and new remedies. In a large New Jersey hospital, supervision of all drug purchasing and formulary development has been turned over to the Director of Pharmacy by the medical board representing no less than 450 physicians. Physicians are being taught slowly but surely to accept the modern "consulting and advisory" role of the pharmacist and to rely more and more on the specialized knowledge and professional judgment of the pharmacy staff. Telephone memos in another well known medical center show

that visiting physicians consult the pharmacy staff on the average of at least once every two visits to the hospital to attend their patients.

How is this significant to us in retail pharmacy? Simple! The same physicians who are being taught to appreciate and respect the professional knowledge of hospital staff pharmacists are the very physicians who are writing prescriptions for our customers. As physician prescription writing habits and inter-professional attitudes are changed for the better, can there be any doubt but that retail pharmacy will be in an increasingly better position to improve its professional services to both the physician and his patients . . . and with greater economy than ever before.

To further relieve the pharmacist of his distressing external "price" pressures, and to counteract the growing volume of socialized medical care propaganda, it is obvious that a comprehensive nation-wide public relations program must be launched at once to sell the public on the tremendous bargain in medical care that they are now receiving from the health professions. The pharmacy field in particular must prove to the public that prescriptions are a good "buy" by any standard.

Let us turn our attention to the ethico-economic problems of substitution, duplication, the use of generic-name nomenclature and the ARB symbols in prescription practice. There is a growing realization in the pharmaceutical field that these internal economic problems are deeply significant and must be dealt with honestly and objectively. It would not be overstating the case to say that the degree to which these problems are understood and the manner in which they are approached and solved will, in the realest sense, determine the course of professional pharmacy for the next 25 years.

To date, discussion of these problems by the various segments of the pharmaceutical field have been characterized by bitter partisanship. Accusations, name-calling, threats and all sorts of gobbeldygook in the name of the profession and public health have served only to becloud and confuse the real issues. In the short time allotted, we will endeavor to clear away some of the debris of confusion and point up the real and basic issue involved.

To see these problems in their proper perspective, one must first understand the nature of their economic origin and background. The 1954 ethical marketing structure—that is, the pattern of selling "ethical specialties" exclusively through physicians by detailing, advertising and medical exhibits, i.e., making sales depend entirely on

physicians' prescriptions and recommendations is grounded almost entirely on the "brand-name" concept. Many observers believe that the slightest weakening of the brand-name distribution concept would drastically modify the marketing structure as we know it today. Whether this would or would not be desirable is quite another question.

Without oversimplifying the economic cause-and-effect picture, we might analyze the situation as follows . . . Prior to the age of "miracle drugs", 70 to 80% of all prescriptions were compounded from drugs in stock; brand-name ethical products played a secondary role in both prescription and inventory dollar volume. By 1953, total ethical drug sales at manufacturers level had risen to $979 million from $149 million in 1939 . . . an increase of 6.5 times with a reversal in the prescription writing pattern so that at present 75 to 80% of all prescriptions dispensed are essentially brand-name specialties. The "miracle drugs", a rapidly growing and aging population, a high level of income, and better health education contributed mightily to the tremendous expansion of ethical drug sales as a whole. On the individual company level, drug production, sales and profits were tied directly to brand-name exploitation.

During this same period—1939 to 1953—firms like Abbott, Eli Lilly, Lederle, Parke-Davis, Sharp and Dohme, SKF, Upjohn, Cutter, Winthrop-Stearns, Wyeth, etc., experienced astronomical increases in total sales, and increases in investment in plant (less depreciation reserve) of up to 600%. In addition, the total number of firms producing medicinal chemicals quadrupled from 1939 to 1953.

Manufacturer profits during these lush years ranged from 18 to 30% of sales before taxes and 12 to 18% after taxes. And research, often considered the life blood of the pharmaceutical industry, has been carried on by the pharmaceutical giants at budgets averaging 3 to 6% of sales and occasionally as much as 10% of the sales dollar . . . a series of calculated, but very highly profitable risks.

In substance, the drug industry had experienced an expansion in sales, productivity and physical size unequalled in pharmaceutical history. Now with sales leveling off as overproduction and competition pare profits, these industrial giants are faced with the problem of maintaining the dollar market for their current stable of products, researching new products and seeking out new (and most likely) foreign markets for surplus production.

While drug sales boomed on the manufacturer level, irregularities in the ethical brand-name marketing machinery went unnoticed or were largely ignored. Manufacturers were not being painfully hurt by such prescription practices as generic-name and ARB, or by the shady practice of substitution. But with the sharp dip in sales following 1951, and the subsequent leveling off of sales during 1952 and 1953, the economic effects of substitution in particular made themselves felt . . . and substitution suddenly became a "cause celebre". The gravity of the manufacturers' situation can best be expressed by a quote from Dr. Klump's address to the DCAT Section of the New York Board of Trade on Jan. 26, 1954, when he said, . . . "The economic effect of substitution, so far as the manufacturer is concerned, is severe. It is depriving us of 10, 20 and even as much as 40% of sales of certain of our products".

Duplication of drug products . . . the production and marketing of drugs and specialties *already* in production and widely marketed by a competing manufacturer is another expression of the same brand-name marketing problem backfiring at a different level. Most reputable pharmaceutical firms engage in the duplication (imitation) of products of a competitor—sometimes by license arrangement—in order to bolster their own sales figures and maintain their market position. Many a firm will imitate products different in name only as a matter of pride.

The isoniazid mess of 1952 is but one of the many examples of free-for-all duplication. In 1953, roughly 517 prescription pharmaceutical products were introduced, of which a little more than 10% were actually new, the rest being "oldies" in new dosage forms or with slight formula changes such as improvement in palatability, new forms, new potencies and new names. A typical example of this kind of me-too competition is Lederle's "improvement" over Lilly's Trinsicon. The improvement in the Lederle product is that the dose in one capsule is equal roughly to two Trinsicon pulvules.

Like substitution, this irregularity in the economics of the ethical marketing structure, went unnoticed while drug stores were experiencing their tremendous expansion of prescription and overall dollar volume. With drug store sales and dollar profits at a high level, the increase in capital investment in slow moving prescription specialty inventory was not felt. But when the growth rate of prescription volume tapered off and both storewide as well as professional profits began slowly shrinking to low levels, the shift of capital and earnings

into expensive prescription inventory suddenly became a critical matter. Of course no one will deny that new drugs and medicines helped to increase retail prescription volume, but the acid test for measuring and comparing returns on capital investment still applies. The pharmacist's objective, like that of any business man (and professional) is to achieve the highest dollar volume and the highest profit on the lowest capital investment.

In the first instance, it was the manufacturer who suffered economic hurt. He found that substitution was an evil that was hurting his sales, and touched upon the supposed inviolability of his brand-name marketing structure. In the second instance, it was the retailer who, when the boom tapered off, discovered that his prescription room was turning into a costly graveyard of me-too, duplicate and fringe promoted specialties. Both segments of the pharmaceutical field began looking for a whipping boy and some goats.

Ethical and public welfare window dressing to the contrary, it is patently clear that the issue between the retailer and manufacturer is joined primarily on economic grounds. Manufacturers have taken the position that they will oppose any act or proposal that would have the ultimate effect of weakening or destroying the economic value of brand-names. These are not mere words. Manufacturers realize that any changes in prescription writing practices (generic-names or ARB) which tend to undermine the brand-name structure of script writing will in the long run reshape their ethical marketing structure. Sales and profits too, are likely to be seriously affected. Knowing what they have and fearing the uncertainty of the unknown, they have every intention of working to maintain the *status quo.* Whether this is possible, reasonable, or desirable in a dynamic economy such as ours raises some good questions.

Pharmacy on the other hand, more sensitive to and affected by external pressures, more vulnerable in the immediate profit and sales sense, resenting bitterly the deteriorating prescription capital returns situation and plain fed up with acting the role of low-man on the ethical marketing and professional totem pole is . . . and mark this . . . at the grass roots level apparently determined to change things. The desire for change seems to be an irrepressible ground swell that some of our retail leaders have yet to catch up with.

Only naiveté and wishful thinking could have kept any observer from anticipating this basic conflict of interests between the retail and manufacturer segments come the day of economic reckoning. I

hasten to add and reiterate that recognition of the real issues of the conflict—*the economic issues*—is probably the first and most important step towards a sound rapprochement. Clothing the real conflict with ethical and moral overtones that have little basis in fact such as is being done by both parties to the conflict, can only aggravate an already explosive situation and contribute little or nothing towards a solution. Might I also add that the cry, ". . . a house divided can not stand", raised with reference to such clearly economic issues is allegorical nonsense. We are no more divided than we ever were. We have only now realized that we each have legitimate competitive interests common to any market in any industry. This is merely an expression of the struggle for economic existence that is common to our American society.

We all agree that substitution *per se* is an evil for which there can never be a valid justification . . . economic or otherwise. Duplication too, may be an evil . . . in that right now it is more often than not an economic waste tied as it is to the brand-name structure. But duplication, *per se,* is hardly an acceptable excuse for substitution. Substitution as such, must be stamped out by governmental, industry and professional policing . . . and it will be. Duplication, however, is a far more complex matter dealing as it does with "free" competition and the problem of Federal legislative and judicial anti-trust policy and must be dealt with by the forces at play in a free economy within pharmacy and the medical profession.

What troubles the manufacturer most deeply, however, is the fact that both the substitution and duplication problems are likely to be solved *by retail pharmacy* at the expense of the brand-name ethical marketing structure that has been so carefully built up. It is only reasonable that manufacturers should prefer to seek out a solution to both problems within the present ethical marketing framework, and the growing feeling that initiative may be slipping out of their hands is reflected in the increasingly violent and bitter denunciations of the generic-name and ARB prescription writing concepts now being taken up and emphasized by retail pharmacy.

As an economist and a teacher, it is not my place to praise or condemn a particular view or position; it is my job to dig out the facts, clear away excess verbiage and interpret those facts by pointing out their significance and relationship to professional pharmacy.

Strangely enough, neither the use of generic-names nor the application of the "Any Reliable Brand" to prescription writing is new

to pharmacy practice. Originally, compounded prescriptions consisted largely of generic-named drugs and chemicals. To a large extent this is still true with compounded scripts, although today we find that in many prescriptions one or more ingredients may be brand-name specialties. The test of reliability, strength and purity of drugs and chemicals was and still is, the USP and the NF. In fact, physicians have always been ready to rely on their own creation (the USP) to set the standards, and on the duly authorized state Boards of Pharmacy and the Federal Food and Drug Administration to enforce these standards. No better watchdogs of public health have ever been devised. By and large, professional judgment of the pharmacist in the selection of the brands of drugs and chemicals he would use in a compounded prescription *was never . . . and is not even now questioned by either the medical profession or the public.*

Hospital pharmacies, dispensing approximately a quarter of a million prescriptions per day, have for years based their prescription dispensing practices on the generic-name, ARB theories. It is common and acceptable practice in most hospitals that when a staff or visiting physician writes a script for a brand-name product, the hospital pharmacist be free to dispense what in his judgment he believes to be an identical or equivalent product if he does not have the brand specified for one reason or another.

Peculiarly enough, the same physician who is purported to suspect the private pharmacist of all sorts of unethical "things", has not lost confidence and faith in the hospital pharmacy or pharmacist, nor does he feel that in the exercise of such professional judgment, the pharmacist is supplanting his judgment, and therein and thereby practicing medicine. As a matter of fact most progressive hospitals use formularies to regulate and guide prescription writing practices for staff and visiting physicians. In most cases there is a tacit acceptance of the ARB and generic-name dispensing practice when the physician enters his patient into the hospital.

It is interesting to note that practically all hospital formularies will not accept for listing any preparation sold under a proprietary name if a drug of identical composition can be obtained under a non-proprietary name. The basic reason for the carry over of the generic-name rule and the ARB understanding in hospital pharmacy to include brand-name script writing is *purely and simply economic.* Any other course of action would, say most hospital administrators, make medicine and drug costs prohibitive and raise bed rates tremendously.

The sources of these prescription dispensing rules and understandings are generally the Pharmacy and Therapeutic Committees composed largely of physicians representing staff and visiting physicians, with the major organizational and drug screening burden carried by the pharmacy directly.

Manufacturers have contended with this generic-name, ARB combination in hospital script practice for decades and somehow adjusted their marketing machinery to cope with this deviation. Of course, individually it puts them at a disadvantage on a competitive brand-name basis as compared with the easier situation in the retail field. In the final analysis, however, the manufacturer with the highest quality product at the most reasonable cost has managed to maintain his position in this market without difficulty.

In proposing the widespread use of the generic-name concept, local and state pharmaceutical groups are not acting radically or thoughtlessly, they are merely carrying over into a *greater part* of their present prescription practice the kind of professional judgment that pharmacy has exercised traditionally with reference to drugs and medicines used in compounded prescriptions.

The "Any Reliable Brand" concept too, has a traditional background. Regardless of the letters or symbols used, it is nothing more than written consent by the prescribing physician to the pharmacist to dispense any brand of a drug which in his professional judgment is reliable (approved by the FDA and in conformity with approved standards) and *identical chemically and therapeutically* with the brand written for. As we pointed out before, with or without such written consent, the hospital pharmacist has in most cases traditionally been empowered to apply this concept to his dispensing practice. When the retail pharmacist calls a physician to request permission to switch brands for one or another reasons, he is in effect applying the ARB concept verbally. When the pharmacist is told by a physician that he may use his judgment as to "brand" on *all* of his prescriptions, that too is an application of the "ARB" concept. Neither situation is uncommon in daily professional practice.

In either event, when a physician prescribes by generic-name or gives the pharmacist permission to use his judgment as to brand-name either verbally or by the written symbols "ARB" *alongside* a brand-name, the physician is pretty sure that his prefabricated specialty prescriptions will be just as legally, honestly and faithfully dispensed as are his compounded prescriptions.

To label either concept of prescription dispensing a form of legalized substitution is to muddy up the true economic issues with confusing and emotional verbiage. To suggest that pharmacists are incapable of exercising traditional professional judgment and responsibility, is to cast doubt on the whole framework of pharmaceutical education, licensure and practice. To suggest that the substandard quality of so-called bootleg and counterfeit drugs and chemicals would become the acceptable standards because pharmacists are freer to exercise professional judgment as to brand-name, chemical composition and therapeutic characteristics, is to discount the intrinsic honesty of the great bulk of practicing pharmacists, and to criticize unfairly the city, state and federal regulatory agencies responsible for supervising and maintaining legal standards for efficaciousness, strength, purity and quality.

The extended application of the generic-name theory and the ARB concept will, as we pointed out before, bring about many changes in the economic picture of the pharmaceutical field. Since space permits discussion of only a few of these changes, we will endeavor to hit only the high points. Of course, what follows might be called by some, using a "crystal" ball . . . but then predicting has always been a privilege and a prerogative reserved to the economist.

Assuming that retail pharmacy grabs hold of, and exploits the generic-name and ARB concepts of prescription writing and dispensing, substitution, as we know it, will for all intents and purposes, cease to be a critical problem. The generic-name and ARB concepts, applied to no less than 90 percent of the pharmacist's prescription practice, will obviate the basic motivation to substitute—economic gain. Of course, where a brand-name product is an *exclusive,* that is, no identical (chemically and therapeutically) product is available, using either the generic-name or ARB concept will make no difference. Here a few foolish and greedy pharmacists might attempt to substitute. Punishment should be swift and sure to repress this unethical practice.

With the growth of generic-name, ARB script writing, the rate of growth of capital investment in prescription inventory will taper off considerably with a consequent improvement in the rate of return on capital and in net profits. Purchases of duplicate brands of chemically identical drugs will be cut considerably with quality, price and service factors playing an important part in the choice of the brand stocked. Free competition plus the assumption of new legal

liability on the part of the retailer with reference to generic-name, ARB dispensing will have an inevitable weeding-out effect on brands now available. Competition among manufacturers on the retail level will tend to stabilize, and perhaps even lower the direct and wholesale cost of much specialty medication.

With a rolling adjustment of materials costs, it is fairly certain that a consumer prescription price adjustment will also take place. This is clearly indicated by the studies we made in developing the Jeffries Prescription Costing and Pricing Calculator. The adjustment could result in a real consumer savings on individual prescriptions, particularly where ingredients costs are high. On the whole, it is fairly certain that the overall total unit and dollar prescription volume *will increase* sharply since physicians will write more freely for their patients. Leading medico-sociologists have observed that even the slightest dip in medical care cost would broaden considerably the base of consumers availing themselves of medical care services and facilities with a consequent increase in tota! expenditures for medical care and proportionate increases for all components including drugs and medicines. In practical everyday terms, our physicians would find observance of the official public-relations admonition against unlimited prescription writing because of high costs, quite unnecessary. It is also obvious that with an increase in the total prescription unit and dollar volume, the expense factor per prescription transaction will decrease, with a consequent improvement in the druggist's professional net profit situation.

On the whole, this could have the effect of minimizing or even eliminating altogether a large part of the external consumer pressures we mentioned earlier and equally important, counteract the surging growth of socialized pharmacy outcroppings such as group physician owned clinics, and union, health insurance and industrially supported dispensaries.

Of course, pharmacists, as individuals, will have to assume to a much fuller extent their professional responsibilities as consultants and advisors to the medical profession. Physicians now rely very heavily on detail men and medical literature for information on new products and answers to pharmaceutical questions. In hospital practice, physicians shift a great deal of this reliance on to the hospital pharmacist. With the extension of the generic-name, ARB concepts, they will be spreading their reliance to the neighborhood druggist, and he must be well prepared to perform this advisory function

competently. Obviously a reemphasis of the consulting-advisory role of the pharmacist will be reflected in parallel reemphasis on this function in the colleges of pharmacy, and in post-graduate technical training.

Since pharmacists will, when the situation permits, exercise professional judgment with reference to the brand of the drug they will finally dispense, it is to be expected that manufacturers' representatives will detail them as carefully and assiduously as they do physicians. In short, while physicians will always remain the primary movers of a drug or medicine, the choice of brand will be with the pharmacist, assuming of course that the drug is competitive. No comment at this point on the significance of this critical change in market emphasis appears necessary, I am sure.

Such problems as return goods, initial prescription size packages of new drugs, unreasonable and frequently uneconomic me-too duplications, price, discount and direct *vs.* indirect distribution are likely to be minimized by the ordinary competitive factors and pressures that go to make up our American system of free competitive enterprise.

The fair trade structure, as such, in so far as it applies to prescription items that are of necessity or design dispensed by brand-names would remain intact. As a matter of fact, the legal status of prescription products under fair trade has long been a subject of speculation and controversy. The legal question raised is whether the prescription package handed to the consumer is covered in view of the fact that it does not normally bear any trade-mark or brand-name. Tablets may carry identifying marks but this is not possible for liquids and powders. The Hoffman-LaRoche Prescription Legend fair trade suit *versus* Schwegmann which was started on February 15 may resolve this perplexing question once and for all. It is interesting to note, however, that no more than 20 to 25% of the average pharmacist's prescriptions are directly affected by the application of the fair trade concept. And, unfortunately, many of those that are fair traded are burdened with unrealistically low minimum resale prices. On this score, Schering should be complimented for upping its fair trade margin to 40% in recognition of this squeeze.

Those who voice the fear that the whole fair trade structure may be seriously undermined by the extension of generic-name, ARB script writing, appear, in the opinion of competent observers, to be speaking more with emotion and veiled threats than with hard facts

and reason. Actually the total volume of prescription legend drugs sold, ostensibly on a fair trade basis, amounts to less than 6% of the total of fair traded drug store sales and a fraction of one percent of *all* retail fair traded sales. Fair trade as such, is in no danger, now or at any time, of being spiked by the extension of generic-name, ARB prescription writing.

A word of caution to those pharmacists who through misguided enthusiasm would rush pell mell into half-baked plans to pile drive generic-name and ARB writing among physicians. The job of selling both of these concepts to physicians is both complex and sensitive. Pharmacy will be dealing with professional and ethico-economic attitudes, patterns and procedures that have, in a sense, become fairly well settled. The fact that approximately 80% of prescriptions are written for by brand-name is an obvious enough commentary on the remarkable job the pharmaceutical manufacturers have done to condition physician script writing patterns, and a true measure of inter-professional reconditioning job that lies ahead for retail pharmacy in promoting the greater use of generic-name and ARB prescription writing.

In developing any prescription writing educational program among physicians, pharmacists should keep in mind the fact that physicians must always feel free to prescribe by brand-name *if they so wish, with full knowledge that their brand-name scripts will be filled exactly as written.* It has already been proven by early proponents of the generic-name, ARB concepts that physicians can more easily be persuaded to use generic-names and the ARB symbols by showing them that an increased use of both concepts over a reasonable length of time is likely to result in an appreciable cut in medical care costs to the consumer, a broadening of the consumer medical care base, and a very definite easing of medical-care-cost pressures on all of the health professions.

To further illustrate the magnitude of the problem of redirecting the physicians' prescription writing habits, it is interesting to note that few, if any, physicians now regard the retail pharmacist as an important primary source of new drug information. On the other hand, more than 47% of 500 physicians questioned in an AMA survey regarded the detailman as their most important source of new drug information. Obviously, the opportunity for intensive development of the retail pharmacist's "drug advisory-consultant" role is tremendous. It is only a question of realizing the professional potential

that lies in the exploitation of this role, and then doing something about it at the local level in terms of a specific program.

We have already pointed to a few of the important economic changes that generic-name, ARB script writing might bring about on the manufacturing level, let us, for a moment, spell them out a little further. Assuming a fairly rapid expansion of generic-name, ARB prescription writing, ethical marketing and promotional patterns will have to be adjusted to conform with the new role of the pharmacist in the distribution of the non-exclusive (presently duplicated and imitated) specialties. To the major pharmaceutical firms with export marketing experience in Central and South American, dealing with retailers who will have the last word on the choice of the "brand" of a particular drug they will dispense on an ARB or generic-name prescription, will be neither shocking nor new, and coupled with experience in domestic institutional sales and promotion, such marketing adjustments should come easily once the principle is accepted. The hardest and most distasteful job for the manufacturer will be swallowing and accepting the notion that the retailer should have a "choice" as provided for by either concept.

At the outset, it is possible that the number of smaller repackaging houses may increase, but despite this possibility, we can be sure that private formula houses are not likely to play any more important a role percentage-wise in the total drug manufacturing picture than they do now. Sharp price competition will undoubtedly compel most manufacturers to reappraise the profitability of each item of their catalog. Many marginal "imitation" brands are likely to be dropped altogether. Duplications with minor changes or additions and combinations of items under a trade-name that could be prepared by the pharmacist by mixing items of the same manufacturer already in stock, will find less acceptance than ever before. In any event we can be sure that efforts will be made by every producer to improve production and marketing efficiency on all products in order to compete price-wise.

It is not at all unlikely that the more progressive manufacturer will, in the course of promoting drugs to physicans, find it more feasible to emphasize the generic-name of the drug along with the trade-name, but in the promotion to pharmacists, emphasize the trade-name as the name to dispense when the doctor prescribes a generic-name drug, or a trade-named drug with the symbols, "ARB" after it.

One well known pharmaceutical economist observed that the

golden age of the "miracle climb" is over and that further drug growth will be on a sharply individual basis with the greatest growth accruing to the company that carries on most successfully, the researching of genuinely new products followed by "exclusive" brand sales and market exploitation on the ethical, wholesale and retail levels. Companies developing patent protected drugs will naturally find it less and less expedient to enter into extensive licensing agreements. In fact, it is likely that recovery of research investment plus profits in due course will depend, to a large extent, on the "exclusive" production and widespread brand-name distribution of the drug. Certainly in an industry that shows such a high rate of innovation and substitution . . . where there are few standard products with well established markets . . . where few products can claim a permanently secure position . . . and where, in the case of competitive products, the first product on the market gains the chance of becoming the top product, *exclusive* production and brand-name exploitation appears to be the soundest and most profitable course to follow.

Total U. S. drug sales volume at the manufacturers level may very well taper off due to the pressure of competition on prices at the wholesale and retail levels. But following the adjustment period, total sales (and particularly, individual company sales) will show a marked improvement as the consumer medical care base increases and more people avail themselves of medical care services and facilities . . . i.e., there are likely to be more *new* users of drugs than ever before in our history. Profits may very well follow the same pattern as sales. In view of the new legal and ethical responsibilities of the retail pharmacist, particularly with reference to the generic-name, ARB concept and in view of the production and marketing know-how of "name" manufacturers, and their ability to meet competition from "all comers", it is not inconceivable that the *now* major manufacturers and distributors will maintain . . . and perhaps even strengthen their hold on the market. A pharmacist faced with the problem of choosing between two or three brands of mephenesin . . . at approximately the same price, would be more likely to choose for his stock item or items, the brand or brands produced by a well-known house because of its many tangible as well as intangible advantages. As long as he stocks a "few", he will stock the items of the so-called "best" or most popular houses.

As we said before, the problem of maintaining the market for all but the patent protected product is bound to become more complex

and expensive *until basic catalog, production, marketing and sales adjustments are made.* Markets will be held (and gained) by increased advertising covering the retailer as completely as the physician; getting greater value from detailing costs; developing different and *needed* forms of an existing "exclusive" or "non-exclusive" drug to achieve maximum marketability; genuinely improving the product itself and constantly lowering the cost of production and distribution to make price more competitive.

One big question arises . . . *what will happen to product research?* Will it be cut down? Will it disappear? Views on this matter differ sharply. Some say that any change in the brand-name economy will compel manufacturers to curb research drastically; other observers feel that fundamental and important pharmaceutical research will not be affected materially, but that overall research costs will be cut by sounder project screening and control. The latter view appears the more reasonable.

While it is true that retail pharmacy should in a sense be grateful that the manufacturers have poured millions into research and developed hosts of new drugs and users, it should also be remembered that research is the life blood of the pharmaceutical industry, and that attaining and maintaining top position sales-wise in the industry for any length of time depended primarily on the ability of research staff to come up with new and needed specialty products. Research is a form of calculated risk that pharmaceutical companies will continue to take, some greater than others . . . *because they can not afford not to.* The effect on sales and on market position of the discovery and "exclusive marketing and exploitation" of such broad spectrum antibiotics as Aureomycin, Terramycin and Chloromycetin by Lederle, Pfizer and Parke-Davis respectively, is too well known to bear repeating. Hope burns ever bright with stockholders and management that perhaps one project of the dozens of "important" projects continually in the works will provide the bonanza "pay-off".

In any event, basic changes in the trade policies and economics of professional pharmacy are in the making. We, as individuals, are living these changes so it behooves us to understand what they are and their significance. It is hoped that responsible leaders in both the manufacturer and retailer levels will come to recognize and understand the nature and significance of the "economic" conflict that has emerged within the pharmaceutical field, and seek an approach and a solution framed in sensible evolution rather than in disruptive revo-

lution. It is fairly certain that manufacturers are more likely to go along with the inevitable economic changes we have discussed, if the pace of change is in direct proportion to their ability to accommodate to those changes both economically as well as structurally. In addition, recognition of the "economic conflict" may very well have the salutary effect of pinpointing those aspects of the problem which require immediate remedial action . . . and which, if handled with wisdom and understanding, could stave off rapid and violent changes.

And finally, as a last thought . . . Looking at the ARB issue squarely, we should, in all fairness to the manufacturers we have been talking about who invest thousands of dollars in the creation of brand-name markets, recognize that the use of the ARB symbol alongside a brand-name does involve such basic considerations as "responsibility of action" and "fairness" above and beyond "right". "Responsibility" in the sense that ARB is a powerful if not explosive economic weapon that must be handled with the utmost of care . . . and "fairness" in the sense that the dispensing of a brand other than that written for with the ARB symbol alongside it, may be *unfair* to the manufacturer —despite the fact that the pharmacist has the physician's written authorization to exercise his judgment with reference to the brand finally dispensed.

Whereas an element of common, competitive unfairness may exist in this practice (or in generic-name practice), to suggest that either fraud or an unfair trade practice, *per se,* is involved is both an extreme and unreasonable view particularly since it is common knowledge that most physicians regard trade-names a little more than convenient descriptive words or tags identifying a specific drug having certain desirable chemical and therapeutic qualities and characteristics.

If this were not the case, it is hardly reasonable to assume that any careful physician would, either impliedly in hospital practice, or actually in private practice knowingly permit to be employed, or knowingly employ the ARB symbol alongside a trade-name. What the physician, in good faith, is saying, is, ". . . I want my patient to take this *kind* of medication since it has the chemical and therapeutic characteristics which he needs . . . And this is the trade-name I am told it goes by. In other words, I *prefer* the brand I mention, but if there are other reliable brands of this particular drug, and you do not have the exact brand written for, you are authorized to dispense whatever brand you have on hand." What other than this can any doctor using the ARB symbol be thinking about when, in the light of the

fullest implications of the ARB concept, he deliberately proceeds to inscribe it on the prescription. Keep in mind that he is *free not to* . . . Should he not use the ARB symbol, the dispensing of any other brand but the exact brand called for would be that most heinous of professional crimes . . . substitution.

What I am suggesting in effect is this: even though the ARB prescription writing and dispensing concept is sound from the point of view of traditional pharmacy practice, and even though pharmacy has every "right" to promote its use universally, without running into substantive legal and ethical difficulties, should pharmacy, in view of the fact that this concept in practice seriously threatens the "rights of others", exercise this "right" without restraint and without giving serious consideration to the entire matter?

In other words, recognizing that Pharmacy has an inalienable right to promote and use the ARB dispensing concept, should we regard the universality of ARB as an end in itself . . . to be achieved at any cost . . . or should we in the spirit of contemplative calmness regard it as merely a means towards an end . . . i.e. . . . a really tough competitive weapon to hold in professional reserve while less drastic steps are taken by all the parties to the controversy to achieve that measure of economic and professional stability Pharmacy needs to better serve the community? The "right", gentlemen, may be ours to exercise, but in all equity, will that "right" be better preserved, by its free and unrestrained exercise?

SELECTED ABSTRACTS

The Use of Neomycin and Polymyxin as Intestinal Antiseptics. Spaulding, E. H., Rao, N. U., Tyson, R. R., Harris, M. J., and Zubrzycki, L. *Bacteriol. Proceed.* page 81 (1954). The use of antimicrobial drugs in intestinal antisepsis is justified only if they increase the effectiveness of purgatives and enemas used to mechanically cleanse the bowel prior to operative procedures, according to the authors. In a study of various antimicrobial drugs they found that daily doses of 200 mg. of polymyxin were ineffective. Daily doses of 3 Gm. of neomycin eliminated coliforms and streptococci but had little effect on the total microbial counts. A dose of 10 Gm. of neomycin and 15 Gm. of sulfathalidine administered within 24 hours produced low counts for a day or two. However, this large dose of neomycin is expensive and it also caused undesirable side effects, even when spread over 3 days. In the latter case the neomycin was combined with 200 mg. of polymyxin a day. This combination also gave good reduction in bacterial counts.

The optimum combination has been demonstrated to be a total dose of 3 Gm. of neomycin and 200 mg. of polymyxin given within a period of 16 hours. Such a dose caused the disappearance of all microorganisms from the fecal contents with the exception of yeasts. The authors stated that combinations with antifungal agents were being investigated in order to attempt to find a means of controlling the yeast count.

The Effectiveness of Erythromycin in Scarlet Fever. Haight, T. H. *J. Lab. and Clin. Med. 43:*15 (1954). In the treatment of 208 naval personnel with scarlet fever, three treatment regimens were employed in strict rotation; erythromycin, procaine penicillin and placebo. Based on the effect on fever, leukocytosis, duration of the rash, persistence of group A hemolytic streptococci in cultures, and in the total duration of the illness there was no significant difference between erythromycin and penicillin. Both antibiotics exhibited an activity in marked contrast to that of the placebo.

The incidence of toxicity reactions was significantly lower among the personnel receiving erythromycin than among those receiving penicillin. A significant number of the patients receiving penicillin developed rashes or urticaria. Two patients receiving erythromycin developed upper abdominal distress and hypermotility of the bowels while another developed frank watery diarrhea. One patient receiving the placebos developed an upper gastrointestinal syndrome similar to that of the erythromycin patients.

On the basis of these studies the author concluded that erythromycin is apparently as effective as procaine penicillin in the treatment of scarlet fever and in the prevention of its suppurative complications. However, the incidence of side reactions with erythromycin was significantly lower than it was with penicillin.

Studies on the Stability of Solutions of Sodium Phenobarbital. O'Reilly, W. J., and Wright, S. E. *J. Pharm. Pharmacol. 6:*253 (1954). Although the decomposition of sodium phenobarbital in aqueous solutions to give phenylethylacetylurea is well known, the authors approached the problem by the use of non-ionic solvents for the estimation of the residual phenobarbital. The dried residue from the solutions of sodium phenobarbital were dissolved in anhydrous pyridine and then titrated with sodium methoxide in dry benzene. Phenolphthalein dissolved in dry methyl alcohol was used as the indicator. It was found that complete recovery was obtained with this method when tested on known samples. It was also found that phenylethylacetylurea did not interfere with the assay.

Using aqueous solutions having a concentration of 5, 10, and 20 per cent sodium phenobarbital, each stored at 5°, 15° and 30° C., it was found that the rate of decomposition was greater than had been previously determined using other methods of assay. It was felt that this non-aqueous assay procedure was more accurate than methods of assay which had been used previously. The percentage loss after 25 days at 5° C. was 0.0, 5.9, and 3.6 per cent for the 5, 10, and 20 per cent solutions, respectively. Stored at 15° C. the loss was 2.0, 6.4, and 4.1 per cent, respectively, and at 30° C. it was 14.0, 17.8, and 13.0 per cent respectively. No measurable loss was found when the solutions were stored at room temperature (15° C.) for up to 10 days, 4 days, or 2 days as the 5, 10 and 20 per cent solutions, respectively.

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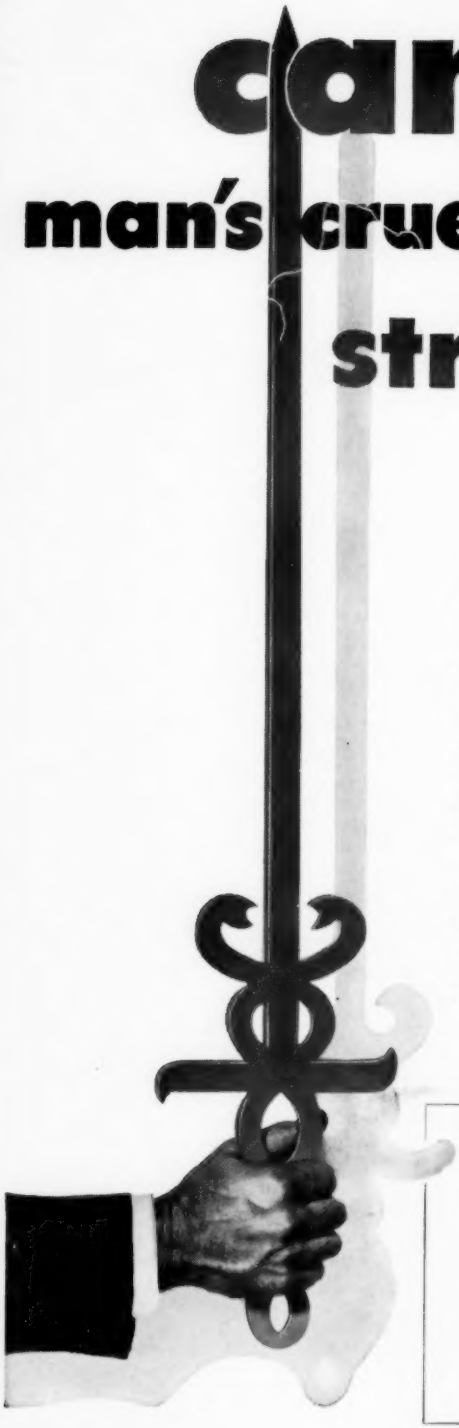

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